HUMAN RESEARCH PROTECTIONS PROGRAM

Waiver of Individual Authorization for Use of Individually Identifiable Health Information

INSTRUCTIONS & COVER PAGE

Federal regulations require that an individual's signed authorization must be obtained before their personally identifiable health information can be released. A waiver of this authorization requirement allows you to use or disclose individually identifiable health information without securing the research subject's signed authorization.

A waiver may be applied for if several regulatory criteria can be fulfilled. One criterion is key: "the research could not practicably be conducted without the waiver." In other words, if it will be difficult or impossible for you to secure a signed authorization from the research subject, you pass the initial test for qualifying for a waiver. Examples of instances where request for a **waiver of authorization** is appropriate include:

- research on existing health information, e.g., medical records research
- research where a waiver of informed consent is also being requested, e.g., survey research via phone

The criteria that must be satisfied for a **full waiver of authorization** are:

- The research could not practicably be conducted without the waiver or alteration of authorization
- The research could not practicably be conducted without access to and use of individually identifiable health information.
- The use or disclosure of health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
- A brief description of the protected health information for which use or access has been determined to be necessary
- An adequate plan to protect the identifiers from improper use and disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
- Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted

Study Title:
Principal Investigator:
IRB #:
Study Approval Date:

1. Describe the specific types of individually identifiable health information (e.g., name, address) to be used in this study and where this information will be accessed:

2. Explain why this research project cannot be carried out without use of individually identifiable health information (why is de-identified information not sufficient?).

3. Explain why obtaining a signed authorization from the research subjects is not practicable.

4. Describe the protections that will be put in place to protect the privacy of individually identifiable health information to be used in this study. What steps will be taken to help prevent accidental use or disclosure outside the scope of this project. This includes information maintained or communicated in electronic, written and oral form.

5. Describe your plan to assure that the individually identifiable health information will not be re-used or disclosed for other purposes.

6. Describe your plan to destroy the personal identifiers at the earliest opportunity or your justification for the need to retain personal identifiers.

I attest that the use or disclosure of individually identifiable health information will involve no more than a minimal risk to the privacy of the research subjects involved in this study and that the information will not be reused or disclosed to third parties unless required by law for authorized oversight of the research study.

Principal Investigator Signature: _____

Date: _____